PTO/SB/21 (03-03) Approved for use through 04/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTINE FOR COM≇/IERCE OF CON#MERCE he Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid D Application Number 10/016,327 TRANSMITTAL Filing Date December 13, 2001 **FORM** First Named Inventor Kirvan, Howard C. Art Unit (to be used for all correspondence after initial filing) 1614 **Examiner Name** Attorney Docket Number 44921-10203 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication Fee Transmittal Form Drawing(s) to a Technology Center (TC) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a **Proprietary Information** After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Terminal Disclaimer Extension of Time Request Identify below): Request for Refund Express Abandonment Request CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Request for Withdrawal as Attorney or Agent with accompanying documents Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Vorys, **\$**ater, Seymour and Pease, LLP Individual Signature Date April 4, 2003 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: Typed or printed Signature Date

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, Washington, DC 20231.

or Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and selectors.

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REQUEST FOR WITHDRAWAL AS ATTORNEY OR AGENT

Application Number	10/016,327	JEOR.
Filing Date	December 13, 2001	A VE
First Named Inventor	Howard C. Krivan	TEO APRO
Art Unit	1614	" SCHOO 9 900
Examiner Name		ENT 003
Attorney Docket Number	44921- 10203	SR 12

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To: Commissioner for Patents Washington, DC 20231						
I hereby apply to withdraw as attorney or agent for the above identified patent application.						
The reasons for this r	equest are:					
Failure of client to respond to repeated requests for instructions & for requests to transfer files to new counsel						
1. The corresp	oondence address is NOT affected b	y this withdrawal.			٦	
2. Change the	correspondence address and direct	all future corresponden	ce to:			
CORRESPONDENCE ADDRESS						
Customer Number				Place Customer Number Bar Code Label Here		
OR			L			
Firm or Individual Name	Mr. Bruce Rose					
Address	Legere Pharmaceuticals, Ltd.				٦	
Address	3123 Research Way, Suite 215					
City	Carson City	State NV		Zip 89706	7	
Country	USA					
Telephone	702-841-1981		Fax	702-841-2263	black	
This request is made on behalf of myself and all the attorneys/agents of record. the attorneys/agents (with registration numbers) listed on the attached paper(s), or the attorneys/agents associated with Customer Number						
This request is enclosed in triplicate (including any attachments).						
Name Thomas R. Boland (Reg. 247093)						
Signature House R. Dollar						
Date April 4, 2003						
NOTE: Withdrawal is effective with	hen approved rather than when received. Unle	ss there are at least 30 days b	etween a	approval of withdrawal and the expiration	1	

This collection of information is required by 37 CFR 1.36. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Thomas R. Boland Direct Dial (202) 467-8802 Facsimile (202) 533-9017 E-Mail - trboland@vssp.com

March 7, 2003

VIA FACSIMILE

Mr. Bruce Rose Legere Pharmaceuticals, Ltd. 3123 Research Way, Suite 215 Carson City, NV 89706

Dear Bruce:

As discussed in our recent conversation, and noted in our letter to you of February 11th, we will no longer be in a position to represent Legere in connection with patent prosecution. Therefore, it is imperative that you retain other counsel so that they can take over this responsibility no later than April 15, 2003. In the interim, the following items require your attention:

44921-10107 – Final response due to office action. We have discussed this matter, and Howard was to send his comprehensive information along with payment no later than March 6. So far, we have received nothing on this matter. We have to present the information to the foreign agent no later than March 10, 2003 If no response is filed the case will become abandoned.

44921-10008 – Final response due to office action. A response is due no later than **April 2, 2003.**

We have written to you with regard to each of these items, but for your convenience, we are attaching hereto a copy of our letters.

We require your instructions and advance payment in order to deal with these matters. Failing your input, we will take no action to keep these cases alive.

Yours sincerely,

Thomas R'. Boland

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March 3, 2003

VIA FACSIMILE

Howard Krivan, Ph.D. Legere Pharmaceuticals, Ltd. 3123 Research Way, Suite 215 Carson City, NV 89706

Re: European Patent Application No.: 96 920 576.4

Applicant: Lectin Biopharma, Inc.

Title: METHOD OF USING LECTINS FOR PREVENTION AND

TREATMENT OF SKIN DISEASES AND DISORDERS

Our Ref: 44921-10107

Dear Howard:

In our telephone discussion of March 3, 2003, Bruce raised the issue of the case due next week. The response is due no later than **March 9, 2003** in the above matter.

In order to respond to this action and issue instructions to the foreign agent, I need your detailed analysis from a technical standpoint. Since time is of the essence, I need to have your response no later than March 6, 2003.

This is very important if we are to retain your rights in Europe.

Yours sincerely,

Thomas R. Boland

TRB/dmf

Enclosures

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07 October 2002

Dr. Howard C. Krivan President Legere Pharmaceuticals, Ltd. 3123 Research Way, Suite 215 Carson City, NV 89706 REWINDER 1/3/03

Re: European Patent Application No. 96 920 576 - Method of Using Lectins for Prevention and Treatment of Skin Diseases and Disorders - based on PCT Application Publication No. WO 96/38162 (priority, U.S. Application No. 08/453,281, 30 May 1995)

Our Ref.: 44921-10107 (formerly 00006)

Dear Howard:

The prosecution of the above-identified European patent application has now progressed to the point that the examiner has issued a first examination report. In order to provide you with a convenient collection of relevant documents we include the following items:

- PCT Published Application
- International Search report and references cited therein
- Supplemental European search report and references (including Legere published applications)
- European examination report with copy of claims as amended for European application (marked to show claims examined)

We have not reviewed the examination report in any detail at this time. You will note that the Examiner has not examined Claims 6, 7, and 9 because they relate to separate inventions which were not searched. He also considers Claim 8, related to treating syphilis, as a separate invention, and does not consider it further. Claims that are removed from consideration as lacking unity can be eventually filed in divisional applications. The Examiner also rejects Claims 10 and 11 (cosmetic method and method of treating body odor, respectively) as not patentable subject matter in Europe.



As to the examined claims, our European associate remarks that the Examiner seems to acknowledge that the cited prior art does not disclose the treatment of the dermis with a lectin, and therefore objects to the medical use claims as lacking inventive step (i.e., obvious), rather than lacking novelty. Our associate also suggests that it may be possible to overcome the Examiner's rejection of Claims 1 and 2 as lacking novelty by amending the claim to recite a "topical composition". (The subsequent phrase "for administering lectins to the skin" is not considered, in European practice, to distinguish the dermal composition from those administered to the eye, etc.) However, the rejection for lack of inventive step (obviousness) will have to be addressed.

The initial term for filing a response to the examination report is set for

09 January 2003.

A two-month extension of time is possible at a cost of about \$300.00. HOWEVER, NO FURTHER EXTENSIONS OF TIME ARE POSSIBLE. FURTHERMORE, CONTINUATION APPLICATIONS ARE NOT POSSIBLE IN EUROPEAN PRACTICE.

Accordingly, a substantive response to this examination report will have to be filed no later than

09 March 2003.

FAILURE TO FILE A RESPONSE RESULTS IN ABANDONMENT OF THE APPLICATION.

The preparation and filing of a substantive response to the examination report with arguments and any amendments to the claims will evidently require extensive review of the prior art (possibly translation of the Russian language reference) and formulation of appropriate arguments. We will then instruct our European associate, who will prepare and file the response. The costs for preparing and filing such a response will be substantial. After consulting with the European associate about his projected costs, we estimate that the expenses of preparing and filing a response may well amount to \$5000.00.

Accordingly, we will not undertake to review and analyze the references without your instructions and advance payment of the costs. Furthermore, in view of the time required for review of the references and formulation of arguments, sending instructions to the European associate, and his efforts in preparing the response to be filed, at least one month must be

allowed for these activities. Last minute instructions will not allow for preparing an adequate response.

We look forward to your instructions for further prosecution of this European application.

Yours sincerely,

Thomas R. Boland

enc.: Examination report

Supplemental European Search Report and references

International Search Report and references

Published PCT application

cc: Dr. R.C. Potter w/enc.

TRB/GWS LEG06L56

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February 21, 2003

VIA FACSIMILE

Dr. Howard Krivan Legere Pharmaceuticals, Ltd. 3123 Research Way, Suite 215 Carson City, NV 89706

Re:

European Patent Appl. No.: 96 905 412.1

Applicant: Legere Pharmaceuticals, Ltd.

Title:

METHOD OF USING LECTINS FOR PREVENTION AND

TREATMENT OF ORAL AND ALIMENTARY TRACT

DISORDERS

Our Ref: 44921-10008

Dear Howard:

This is to give you advance notice that the final due date for response to the outstanding Office Action is April 2, 2003. Attached is a copy of our letter of November 6, 2002, which sets out the substance of the Office action. In deciding if you want to pursue this matter, please note the anticipated costs on page 3 of our letter.

Also please note our letter of February 11, 2003, regarding the discontinuance of services in connection with patent prosecution. It will be necessary to inform the foreign agent of this fact and identify a new instructing counsel in the US.

It is extremely important that you attend to this matter right away.

Yours sincerely,

Thomas R. Boland

Enclosures

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06 November 2002

Dr. Howard C. Krivan President Legere Pharmaceuticals, Ltd. 3123 Research Way, Suite 215 Carson City, NV 89706

REMINDER 1/2/02

European Patent Application No. 96 905 412.1 - Method of Using Lectins for Prevention and Treatment of Oral and Alimentary Tract Disorders - based on PCT Application Publication No. WO 96/24368 (priority, U.S. Application No. 08/385,306, 07 February 1995)

Our Ref.: 44921-10008 (formerly 44921-00006)

Dear Howard:

The prosecution of the above-identified European patent application has now progressed to the point that the examiner has issued a first examination report. In order to provide you with a convenient collection of relevant documents we include the following items:

- PCT Published Application
- International Search report and references cited therein
- Supplemental European search report and references)
- European examination report with copy of claims as amended for European application. Note that the claims have been amended and their number has been reduced according to European practice, which permits multiple dependent claims but does not permit claims to methods of treatment practiced on the human body.

We have not reviewed the examination report in any detail However, we paraphrase below the initial comments made by our European associate attorney on the European examination report.

The Examiner suggests that the claims are lacking in novelty based on three prior publications. Document D1 (European Patent Application No. EP-A-481701, "the '401 application") comes from the International Search Report (incorrectly identified therein, as the examiner points out).

Documents D2 (Weinberg et al., Interaction of *Treponema denticola* TD-4, GM-1 and MS25 with human gingival fibroblasts, <u>Infection and Immunity</u> 1990, 58(6), 1720-1729 (June 1990), "the Weinberg reference") and D3 (U.S. Patent 4,742,046, to Bliah, "the '046 patent") are taken from the European Supplementary Search Report.

All of these cited references disclose the binding of lectins to infective agents, either bacteria or viruses. However, the Examiner's assessment of D1 (the '401 application) does not take full note of its actual disclosure. Although it shows the binding of lectins to infective agents, there is no indication that this is itself of therapeutic value. The lectins are used to bind a liposome to infective material, and the antibacterial or antiviral activity is provided by another material carried in the liposome.

Document D2 (the Weinberg reference) is perhaps the most relevant prior art since it shows the binding of lectins to $T.\ denticola$, which is mentioned in the present application. However, your comments are welcome on whether there is any suggestion that the binding of the lectin suggests an anti-infective therapy.

The Examiner suggests that the prior art disclosures mean that there is nothing inventive left in the present application. However, the biological data present in the application shows activity against the significant microorganism *H. pylori*, and possibly this could be used as the basis of a claim which is both novel and inventive over the cited art.

The Examiner raises some relatively minor matters in paragraphs 4 and 5 of the report. The matters raised in paragraph 5 can be dealt with when your comments are available on the prior art and possible amendments to distinguish from it.

With regard to paragraph 4, "sWGA" has been identified in the description as "suc-WGA" and "Lotus" has been identified as "LTA". As for the suggestion that "PSA" can be confused with another material, we can argue that in a claim that is explicitly referring to lectins, "PSA" will be understood as being the lectin identified in the description.

Dr. Howard C. Krivan

- 3 -

44921-10107 EP

The initial term for filing a response to the examination report is set for

02 February 2003.

A two-month extension of time is possible at a cost of about \$300.00. HOWEVER, NO FURTHER EXTENSIONS OF TIME ARE POSSIBLE. FURTHERMORE, CONTINUATION APPLICATIONS ARE NOT POSSIBLE IN EUROPEAN PRACTICE.

Accordingly, a substantive response to this examination report will have to be filed no later than

02 April 2003.

FAILURE TO FILE A RESPONSE RESULTS IN ABANDONMENT OF THE APPLICATION.

The preparation and filing of a substantive response to the examination report with arguments and any amendments to the claims will evidently require extensive review of the prior art and formulation of appropriate arguments. We will then instruct our European associate, who will prepare and file the response. The costs for preparing and filing such a response will be substantial. We estimate that the expenses of preparing and filing a response may well amount to \$5000.00-\$6000.00.

Accordingly, we will not undertake to review and analyze the references without your instructions and advance payment of the costs. Furthermore, in view of the time required for review of the references and formulation of arguments, sending instructions to the European associate, and his efforts in preparing the response to be filed, at least one month must be allowed for these activities. Last minute instructions will not allow for preparing an adequate response.

We look forward to your instructions for further prosecution of this European application.

Thomas R. Bolland

enc.: Examination report

Supplemental European Search Report and references International Search Report and references Published PCT application

cc: Dr. R.C. Potter w/enc. TRB/GWS

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February 11, 2003

CERTIFIED MAIL – RETURN RECEIPT

Mr. Bruce Rose Howard C. Kirvan, Ph.D. Leger Pharmaceuticals, Ltd. 3123 Research Way, Suite 215 Carson City, NV 89706

Re: Patent Law Representation

Dear Bruce and Howard:

Our Firm has given considerable thought to how we want to restructure the patent practice which we have been conducting for many years. We have retained consultants to assist us in this deliberation and, in the end, the Firm has decided to discontinue all patent prosecution aspects of our practice. As you probably know, patent prosecution includes searching prior art for patentability, preparing patent applications and dealing with the Patent and Trademark Office or foreign regulatory bodies in the course of obtaining a patent, and maintaining patent applications and issued patents by attending to annuity and maintenance payments.

We will continue our practice of general counseling, providing infringement and validity opinions, and litigation in the Federal Courts. However, we will no longer be involved in that part of the practice described above.

Attached is a list of those applications which we have handled on your behalf. Also enclosed is a list of those cases requiring annuity payments and/or maintenance fees, which we have been processing through Computer Packages Annuity Service, Inc. (CPI).

With regard to the pending applications, it will be necessary for you to retain other counsel by **February 28, 2003**. In each case, a Revocation of Power of Attorney will be necessary, and we have enclosed herewith a document for each individual case. Please sign the document where indicated and return the executed copy to me by return mail or facsimile, so that they may be promptly filed in the United States Patent and Trademark Office or other relevant agencies. At that point, I will send the relevant files to you or to your designee. If you have

February 11, 2003 Page 2

retained other counsel, they may advise you on the type of revocation they would prefer, and in that case they would undoubtedly wish to file the revocation themselves.

With regard to the annuity and maintenance payments, I suggest that you either contact CPI directly or assign the responsibility for payment to your new counsel if that is the case. CPI's address and relevant information is as follows:

Computer Packages Annuity Service, Inc. 414 Hungerford Drive Rockville, MD 20850 Telephone: 301/424-8890

Facsimile: 301/762-8663

Please note that Legere/Lectin Labs continues to have outstanding debt to the Vorys Sater firm. A ledger sheet is attached to show the extent of that obligation. Please pay this amount in full as soon as possible.

If you wish to discuss the matter further, please let me know.

Yours sincerely,

Thomas R. Boland

TRB/dmf

Enclosures